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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JOHN R VAN AMSTERDAM
WOLF GREENFIELD & SACKS
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/462,929	OLD ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006 and 06 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67 and 124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67 and 124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 67 and 124 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co.,*

Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

3. A review of the disclosure fails to find a teaching of where the polynucleotide represented by SEQ ID NO: 681, or any of the multitudinous 24mers that are contained therein, are taught as being useful in any specific assay. In short, the specification has not set forth reaction conditions and starting materials that would enable the use of the claimed polynucleotides in a method that would satisfy the requirements of 35 USC 101. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
>
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a

> specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

4. In view of the general absence of a reproducible method for the use of the claimed nucleic acid, the specification is deemed not to enable its use. Similarly, with the specification not setting forth any method for the use of the polynucleotide or its fragments, the specification has not also set forth the best mode contemplated by applicant.

5. Claims 67 and 124 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well-established utility.

6. A review of the specification fails to locate where applicant has associated any specific and substantial or well established utility with SEQ ID NO: 681, or of fragments, and their complements, thereof.

7. Claims 67 and 124 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to argument

At pages 4-6 of the response received 19 July 2006, applicant's representative asserts that the invention is in fact adequately described as the claim is limited to a specific SEQ ID NO., and those nucleotides that are comprise at least 24 consecutive nucleotides of SEQ ID NO. 681. Argument is also presented at page 6 of the response that "to the extent that there was a best mode known to applicant, this has been set forth in the specification.

The above response has been fully considered and has not been found persuasive as applicant has not identified where the specification describes those fragments of 24 or more consecutive nucleotides of SEQ ID NO. 681 that were known to be useful at the time of filing. In support of this position, it is noted that a search of oligonucleotides of SEQ ID NO: 681 has identified numerous instances of where a sequence found in SEQ ID NO: 681 matches perfectly with a non-human sequence. See below.

39	29	1.7	435	2	AAV23695	Aav23695 Plant CBG
40	29	1.7	435	2	AAZ06908	Aaz06908 Pine coni
41	29	1.7	435	3	AAA67983	Aaa67983 Pinus rad
42	29	1.7	435	10	ADD41733	Add41733 Coniferin
43	29	1.7	435	14	AED59833	Aed59833 Pinus rad

As can be seen above, there are 5 instances of where an oligo of 29nucleotides in length, found in a plant, matched perfectly the same nucleotide sequence found in applicant's SEQ ID NO: 681. While applicant has asserted that the claimed nucleic acids are to be useful in the identification of cancer associated antigen through the use of autologous antibodies, it is noted that the claims do not require the oligonucleotides to encode the same antigen as that of SEQ ID NO: 681.

While argument is presented that the Summary of the Invention "makes it clear that 'the invention has in vivo and in vitro uses," a review of the response as well as of the specification fails to locate where the specification identified useful oligonucleotides, and more particularly,

identified which of the 1,722 oligomers of 24 nucleotides in length are actually useful for any of the intended uses. Similar issues exist with respect of the 29mers, which as shown above, clearly do not relate in the slightest to the intended utility.

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 112, first paragraph, is maintained.

At page 6, bridging to page 7 of the response received 19 July 2006, applicant's representative asserts that the oligos claims have utility as asserted at page 20, lines 20-30, of the specification. Argument is also presented that the fragments have been previously described as allowing for the identification of "region of a gene that encodes peptide that induces an immune response."

The above argument ahs been fully considered and has not been found persuasive. A review of the specification as filed finds the following passage at page 20, lines 20-30, of the specification.

> linker sequences if desired. The polytope is processed to generated individual epitopes which are recognized by the immune system for generation of immune responses.
>
> Thus, for example, peptides derived from a polypeptide having an amino acid sequence encoded by one of the nucleic acid disclosed herein, and which are presented by MHC molecules and recognized by CTL or T helper lymphocytes, can be combined with peptides from one or more other cancer associated antigens (e.g. by preparation of hybrid nucleic acids or polypeptides) to form "polytopes". The two or more peptides (or nucleic acids encoding the peptides) can be selected from those described herein, or they can include one or more peptides of previously known cancer associated antigens. Exemplary cancer associated peptide antigens that can be administered to induce or enhance an immune response are derived from tumor associated genes and encoded proteins including MAGE-1, MAGE-2, MAGE-3, MAGE-4, MAGE-5, MAGE-6, MAGE-7,

It is noted with particularity that the claims do not require the oligonucleotides to encode any antigen, be it associated with any specific protein or not. Even if the claims were so limited, it is further noted that the specification does not identify which regions of SEQ ID NO: 681 are associated with any antigenic determinant. As associated above, there are numerous instances of 29mers that are found in plants. Even if the claims were so limited, the specification is silent as to just which oligonucleotides of 24 consecutive bases or more of SEQ ID NO: 681 are associated with any of the specific proteins.

While argument ahs been presented that the nucleic acids could be used in a Northern blot, Southern blot, or as primers, such is true of all nucleic acids, and does not in and of its self constitute a specific, substantial, and credible utility as the detection or amplification of a nucleic acid that has no utility does not in turn impart utility to the probe or primer used in the method. For the above reasons, and in the absence of convincing evidence to the contrary, claims 67 and 124 remain rejected under 35 U.S.C. 101.

8. Claims 67 and 124 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in

> the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

9. A review of the specification fails to locate an adequate written description of those fragments of SEQ ID NO: 681 that are at least 24 nucleotides long, and which meet the requirements of 35 USC 101. While the nucleotides encompassed by SEQ ID NO: 681 are clear, the specification's silence as to which fragments are useful is not to be found. Accordingly, one of skill in the art would not be able to recognize those fragments are useful from those that are not. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

10. Claim 124 has been interpreted as encompassing not only the polynucleotide associated with SEQ ID NO: 681, but also any and all possible degenerate variants. A review of the disclosure, however, does not locate any teaching of just what the coding sequence of SEQ ID

NO: 681. Not knowing what the coding sequence is, one would not be able to readily identify just what are the degenerate variants, much less be able to use same, *supra*.

11. For the above reasons, and in the absence of convincing evidence to the contrary, claims 67 and 124 remain rejected under 35 USC 112, first paragraph.

Response to argument

At pages 8-10 of the response received 19 July 2006, applicant's representative asserts that the specification does adequately describe the invention as all possible oligonucleotides of 24 nucleotides or more can be readily determined by one of skill in the art be referencing SEQ ID NO: 681.

While agreement is reached in that the specification does provide the nucleotide sequence of SEQ ID NO: 681, and that one could determine what are possible oligonucleotides of said sequence, the specification does not identify or describe in any manner just which of the thousands of possible oligonucleotides are in fact useful for any of the non-specific purposes identified. As set forth above, numerous fragments of 29 nucleotides of SEQ ID NO: 681 are recognized as being associated with plants, not just cancers. Rather than providing a full, clear, and concise description of those nucleic acids that are useful, and specifically describe just what that use is (and enabling these uses), applicant is seemingly shifting the burden of providing the description of the invention from self to the shoulders of the public. Such non-specific identification of fragments and of their uses does not constitute an adequate written description of the invention.

12. For the above reasons, and in the absence of convincing evidence to the contrary, claims 67 and 124 remain rejected under 35 USC 112, first paragraph.

Conclusion

13. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS